STATE MEDICAID P&T COMMITTEE MEETING

THURSDAY, August 16, 2012
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114

MINUTES

Committee Members Present:

Kort Delost, R.Ph.
Lisa Hunt, R.Ph.
Bernadette Kiraly, M.D.
Jameson Rice, Pharm.D.
Beth Johnson, R.Ph.
Roger Martenau, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Robyn Seely, Pharm.D.
Tim Morley, R.Ph.
Bobbi Hansen, CPhT.

University of Utah Drug Information Center Staff Present:

Melissa Archer, Pharm.D.
Gary Oderda, Pharm.D.

Other Individuals Present:

Mary Piersanti, unaffiliated patient advocate
Jeff Piersanti, unaffiliated patient advocate
Deb Berry, unaffiliated patient advocate
Ginger Johnson, Happy Chemo
Steve Fox, GSK
Sabrina Aery, BMS
John Ward, UofU physician
Brad Burgstakker, Elan
R Akrtyn MD
C Kohn, GSK
Brooks Hubbard, Boehringer Ingelheim
Kim Eggert, Gilead
Michelle Bice, Gilead
Scott Goldfarb, GSK
Kristi Adams, GSK
Eric Kimelblatt, Gilead
Joe Brougham, GSK
Charissa Anne, J&J
Matthew Chin, PORC
Lori Honcerth, Bayer
Barbara Boner, Novartis

Meeting conducted by: Lisa Hunt.

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1 Review and Approval of Minutes: Kort Delost made a motion to approve the July minutes. Beth Johnson seconded the motion. The motion was approved unanimously.

2 Lisa Hunt described how other states manage antineoplastic drugs. Iowa uses a "Recommended Drug List" (RDL), which identifies drugs that are recommended as first line agents. No prior authorization (PA) is required for drugs not on the RDL. Maine uses a "traditional" PA process. Vermont requires that all antineoplastic drugs be ordered

through a specialty pharmacy, but has no other requirements.

3 Lisa Hunt very briefly described the role of the Committee and how drug classes are chosen for review, for the benefit of attendees who may not be familiar with the process.

4 Drug Utilization Review (DUR) Board update: Robyn Seely addressed the committee. She reported that the DUR board last met on Thursday August 09, 2012, but a quorum was not assembled. Amlodipine and other QT-prolonging drugs were informally discussed, and will be addressed in September's meeting.

5 **Antineoplastic Urinary Tract Protective Agents:** Melissa Archer provided an overview of the two agents currently approved in the United States, mesna (Mesnex®), and amifostine (Ethyol®). Mesna is available PO and IV, and is indicated to reduce hemorrhagic cystitis of the kidney and bladder, associated with ifosfamide or cyclophosphamide therapy. Amifostin is available IV and is indicated to reduce renal toxicity associated with repeated cisplatin administration, and to reduce xerostomia in patients undergoing radiation for head and neck cancer. The University of Utah Drug Information Center recommended including both agents on the Preferred Drug List (PDL).

Public Comment: No public testimony was offered.

Motions: Beth Johnson made a motion that the two drugs are equally safe and efficacious, although they have different indications. Jameson Rice seconded the motion. The motion was approved unanimously. Kort Delost made a motion to include both drugs on the PDL. Beth Johnson seconded. The motion was approved unanimously.

6 **Antineoplastic Mitotic Inhibitors:** Melissa Archer provided an overview of the following agents: cabazitaxel (Jevanta®), docetaxel (Docefrez™, Taxotere®), estramustine (Emcyt®), ixabepilone (Ixampra®), paclitaxel (Taxol®, Abraxane®), vinblastine (Velban®), vincristine (Vincasar PFS®), and vinorelbine (Navelbine®). Although in the same class, each agent has specific indications, adverse effects, and other properties. The University of Utah Drug Information Center recommended either a RDL similar to Iowa's, or including all the agents on a PDL.

Public Comment: Joseph Brougham of Bristol-Myers Squibb testified on behalf of Ixampra®. He reviewed its indications, boxed warnings, efficacy (trial) data, and adverse effects.

Public Comment: Ginger Johnson, founder/president of Happy Chemo. Inquired if any Committee members are "experienced cancer chemotherapy physicians", and/or if any had received chemotherapy. Ms. Johnson pointed out that each patient's body is different and that each reacts to different drugs in different ways. She appealed to the Committee on a personal level, relating experiences of her own and of her loved ones. As she

understands it, a nurse often spends up to "twelve hours" "fighting" with insurance companies regarding a PA that may or may not be approved. She draws parallels with "Lord of the Rings" and encourages the Committee not to approve "one ring [agent] to rule them all".

Lisa Hunt responded to Ms. Johnson's testimony, lamenting Ms. Johnson's personal experience. Lisa reminded the Committee and attendees that Utah Medicaid is not an insurance company, although it does reimburse for some medical care. Utah Medicaid is federally mandated to cover all outpatient drugs that are rebateable. Utah Medicaid insures transparency in the pharmacy program by openly publishing the PDL, PA criteria, and other key information online. In addition, Utah Medicaid provides an approval or denial of a PA request within 24 business hours of receipt.

Public Comment: Debbi Berry, unaffiliated citizen. Ms. Berry has had cancer and is a registered nurse. She questions why Utah Medicaid is considering a PDL for these agents, and observes that Medicare and/or private health insurance companies often follow the example of State Medicaid programs. She mentions that she was asked to "step down" from a position at her work for reasons related to her cancer, and that she is now able to work but also has disability benefits. She says it is not cost effective to require step-type therapy. She mentioned that her doctor told her of a case in which an LPN spent twelve hours working on a PA request, and that if that were true of all requests, he "would go out of business". She notes that more and more people are getting cancer at younger and younger ages, and that cancer is "running rampant".

Board Discussion: Kort Delost agreed with the testimonies offered in that cancer treatment is very individualized and is treated with combination therapy. He suggested that Utah Medicaid cover all the antineoplastic mitotic inhibitors as preferred agents. He noted that it is difficult to compare the safety and effectiveness of these agents because they have different indications and effects.

Board Discussion: Beth Johnson reminds the Committee that cancer is an emotional topic, but all illnesses and drugs deserve the same respect and analysis. She states that "as stewards of public funds", the Committee must weigh the costs and benefits of the various agents. She practices in oncological pharmacy and understands how the drugs work, and believes they require careful oversight. She notes that the National Comprehensive Cancer Network (NCCN) guidelines are updated regularly and provide excellent guidance, including the use of some drugs over others. She points out that oncology treatments are expensive – drugs, physicians, patient protection, supplies, etc all contribute to ever increasing costs. She agrees with Kort Delost in that each drug has its own niche, but points out that the many drug shortages in today's market force decisions regarding alternative treatments (in all clinical areas). She encourages the Committee to think logically about the benefits versus the risks of the various agents. She points out that many of these drugs carry with them a large burden of adverse effects, while extending lives incrementally, as Joseph Brougham mentioned. She says that Utah

Medicaid must serve its patients in the best possible way with the money allotted. Returning to Kort Delost's point, she suggests that we need to trust the oncologists to have genuinely evaluated each individual case, and to have prescribed only the treatment that they believe is best, in their clinical judgment. She suggests that the Drug Utilization Review Board look at each class of antineoplastic agents, with the possibility of "stratifying" the classes. She also urges Lisa Hunt to evaluate and try to maximize rebates on these drugs.

Lisa Hunt asked the Committee their opinion of Iowa's RDL approach. The Committee questioned the utility of a RDL, if non-recommended drugs do not require a PA. Beth Johnson cautioned against Maine's policy of acquiring antineoplastic medications (oral and otherwise) through specialty pharmacies only, and Kort Delost concurred that such a policy might hinder access to the drugs.

Motion: Kort Delost motioned that none of the drugs are really "safe", but they can be effective for their given indication(s). He also motioned that, because different therapies are so individualized, none of the medications should be excluded. Bernadette Kiraly seconded both motions.

Discussion: Question from Ginger Johnson, founder/president of Happy Chemo: Under what authority can Utah Medicaid institute a RDL? Lisa Hunt stated that Utah Medicaid is a single-state agency created to administer Medicaid. Ginger Johnson stated that to her understanding, Utah Medicaid can create a PDL, but not to create a RDL. Lisa Hunt stated that there is nothing that prohibits the Committee from making recommendations to Utah Medicaid. Lisa Hunt reminded the audience that the Committee members have <u>not</u> recommended a RDL.

Discussion: Comment from Debbi Berry, unaffiliated citizen: She states that "I disagree that it's not cost effective to question these drugs". She reiterated her previous comment that it is not cost effective to require step-type therapy.

Discussion: John Ward, oncologist, Huntsman Cancer Institute, member of the NCCN guidelines panel for breast cancer: He believes that NCCN guidelines make Utah Medicaid's job easier, because CMS accepts, for payment, regimens that follow the guidelines. The NCCN also considers cost in their establishment of preferred and alternate agents. He suggests that the NCCN can be trusted to vet the treatments, and the University of Utah health care system would appreciate Utah Medicaid's support of their guidelines.

Motions: The motions (see third paragraph of this page) were approved unanimously.

7 Pharmacy Policy Department Comment: Tim Morley addressed the attendees and provided some education. The Medicaid program, particularly the PDL program, is often perceived as interested only in costs. Although the perception is that none of the

Committee members are oncological specialists, each has a basic understanding of the principles involved. In order for all in attendance to be very clear, Tim Morley reiterated that the accepted motion was to include all the agents on the PDL. This clinical recommendation is Utah Medicaid's "defense" if asked why costs (in this case, for cancer treatments) aren't at the very minimum. Tim Morley states that the Committee does not gather in order to "arrive at a pre-conceived solution". The purpose of the Committee is to provide the clinical recommendations that Utah Medicaid needs in order to support clinical policy. Tim Morley thanked the Committee for their work and expertise, recognizing that they are not compensated in any way.

Pharmacy Policy Department Comment: Tim Morley continued his comments, addressing the Accountable Care Organization (ACO) model that the State has instructed Utah Medicaid to adopt. Managed Care Organizations (MCO) currently exists within the medical benefit, while pharmacy has traditionally been "carved out". On January 01, 2013, pharmacy will become part of managed care in Salt Lake, Utah, Davis, and Weber counties. Mental health and immunosuppressant drugs will remain "carved out", because legislation prevents a PDL to be created for them. Hemophilia drugs will continue to be "carved out", as they are already part of a disease management program. The other counties in Utah will continue to operate the Fee-For-Service model. Utah Medicaid is still negotiating computer programming and data-sharing details with the administrators of the ACOs: HealthyU, Select Health, Molina, and Healthy Choices (Iasis). On October 01, 2012, enrollment will begin. Each plan has the potential to create its own formularies. Four plans with three benefit types each yield a potential 12 different PDLs. The change to ACOs is a large and complicated undertaking, and is not being treated lightly.

Next Meeting Set for Thursday, September 20
Meeting Adjourned.
Minutes prepared by Robyn Seely.